10.0 QUALITY ASSURANCE

The primary definition of DOE policy concerning quality assurance (QA) is found in DOE 5700.6B. The Order sets forth principles and assigns responsibilities for establishing, implementing, and maintaining programs of plans and actions to provide quality achievement in DOE programs. It is applicable to all DOE programs; however, it does not specifically refer to environmental surveillance and monitoring activities. It specifies that QA activities be identified through the judicious and selective application of appropriate, recognized standards. It identifies American National Standards Institute/ American Society of Mechanical Engineers (ANSI/ASME) NQA-1 as the preferred standard for nuclear activities. Most DOE effluent and environmental monitoring is performed by contractors. The Order specifies that the DOE field organization and project office managers have overall responsibility and authority for defining and ensuring effective implementation of required QA activities to be established and implemented for DOE programs by contractors under their direction. DOE 5700.6B requires the development of QA Plans. In addition to these plans, the Environmental Monitoring Plan *should** contain a section on QA and *should** cover the monitoring activities at each site, consistent with applicable elements of the 18-element format in ANSI/ASME NQA-1.

The purpose of this section is to define the QA activities that are applicable to DOE monitoring and surveillance programs and to specify the requirements. Discussed are the application of QA and quality control (QC) practices, which are defined in DOE Orders, environmental legislation, consensus standards, and technical references.

Quality control is a task-specific activity that provides verification of quality of a product or service, as opposed to QA, which provides assurance of this quality. The definitions of both QA and QC are provided in DOE 5700.6B under the QA definition.

Quality control is generally performed by the line organization as part of its design or implementation functions. Quality assurance is, in part, an evaluation function that *should* be performed by an independent organization. Verification of the quality of a product or service is an evaluation function that is performed by persons or organizations not directly responsible for performing the work. Even though these two functions (QA and QC) can be considered separately, they are both necessary parts of a quality program.

Two terms used in the description of QA activities are "control" and "verification." Control is the act of identifying, reviewing, approving, documenting, and verifying the status of items affecting quality. Verification is the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

10.1 MANDATORY QA REQUIREMENTS

DOE 5700.6B states that national consensus QA standards are to be applied where suitable ones are available, and in the nuclear area, ANSI/ASME NQA-1 is the preferred standard. This standard can be applied in a selective manner, depending on the complexity and significance of the particular program or project activity. The QA Plan is the mechanism to be used for selectively applying QA requirements to the effluent and environmental monitoring programs.

10.1.1 QA Plan

A QA Plan for environmental monitoring is required by DOE 5400.5 as a part of the Environmental Monitoring Plan to be prepared for each DOE-controlled site. Depending on the size of the monitoring program, it might be appropriate to prepare separate sections for each major component of the monitoring program, such as effluent, environmental, ground water, etc. This plan *should* specify the control elements (for QC) that will be applied to the monitoring activities. The QA Plan does not have to contain all procedures, guides, quality controls, calibration procedures, etc., but rather it *should* reference the control elements and assign responsibility for each of the applicable 18 criteria of ANSI/ASME NQA-1. The elements of ANSI/ASME NQA-1 might not all be applicable to the monitoring programs. In that case, a statement qualifying the nonapplicability or a reference to the organization that is responsible for the particular element will be sufficient. The QA Plan *should* be prepared in conjunction with or approved by the QA organization of the site.

10.1.2 Audits

Periodic audits *should** be performed to verify compliance with operational and QC procedures. The frequency of audits *should* be determined jointly with the site QA organization. The following requirements from ANSI/ASME NQA-1 *should** be followed:

> Planned and scheduled audits *should** be performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness. These audits *should** be performed independently in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited (i.e., supervisors cannot audit their own facilities). Audit results *should** be documented and reported to and reviewed by responsible management. Follow-up action *should** be taken where indicated.

10.1.3 Elements of the QA Plan

The elements of a QA program plan *should** be derived from the 18 criteria in ANSI/ASME NQA-1 and those stipulated in 10 CFR Part 50.

10.2 APPLICABLE EXISTING QA REQUIREMENTS

There are existing requirements for QA on all DOE programs, including monitoring and surveillance activities. In addition to DOE 5700.6B, these requirements come from DOE field organization orders, contractor corporate QA programs, and environmental legislation QA requirements.

10.2.1 DOE Field Organization Orders

The DOE field organizations (Operations Offices) have issued orders that establish QA policy and responsibility within the field organizations and establish requirements for QA programs for contractors. These requirements specify that QA Implementation Plans (as defined by DOE 5700.6B) be established and implemented for each project and program. These plans are specified as a document identifying the requirements, judiciously selected from the overall QA program, that are applicable to a particular program or project.

10.2.2 Contractor Corporate QA Programs

The system of DOE Orders (Headquarters and field organizations), as described above, specifies that contractors implement QA programs. DOE 5700.6B requires the preparation of QA implementation plans for assigned projects. Facility managers are to verify implementation of the QA program and plans through audits and appraisals. They are also to provide that QA requirements are incorporated into contracts, work orders, and purchase orders issued under their authority as DOE contractors. All contractors performing environmental and effluent monitoring are required to have QA programs in place that meet the general DOE QA requirements.

10.2.3 Environmental Legislation QA Requirements

Environmental legislation, such as the Safe Drinking Water Act and the Clean Air Act, includes requirements for using EPA-approved procedures for monitoring. These monitoring procedures include sample-collection methods, sampling frequency, sample analysis, data reporting, dispersion models, and dose calculations. Monitoring to demonstrate compliance with these environmental laws incorporates the QA/QC requirements that are specified by the EPA. References such as those by the Health Physics Society Committee (1980), Inhorn (1978), NRC Regulatory Guide 11.15, Oakes et al. (1980), and Taylor and Stanley (1985) contain useful guidance on QA programs that involve monitoring and surveillance.

10.3 QC GUIDANCE

Specific operational and QC program procedures are required to be documented in the site Environmental Monitoring Plan. The paragraphs that follow describe these procedures and programs.

10.3.1 Written Monitoring Procedures

Required written procedures covering monitoring activities include the following topics:

- Environmental and effluent sampling
- Ground-water sampling
- Continuous environmental and effluent monitoring systems
- Laboratory analysis
- Data management and calculations
- Transport and pathway modeling
- Dose calculations
- Review and reporting of results.

10.3.2 Analytical QC Program

Each site is required to maintain an analytical QC program adequate to document and control the accuracy and precision of the analytical results. If analytical work is performed by a subcontractor, the subcontractor is required to meet the same QC requirements. Guidance on content of analytical QC programs is provided by Belanger (1984), Goldin (1970), Rosenstein and Goldin (1964), EPA-600/9-76-005, EPA-600/7-77-088, EPA-600/8-78-008, and EPA-600/4-79-019.

DOE 5400.5 requires that all organizations performing effluent or environmental monitoring participate in the DOE quality assessment program for those nuclides and media that they regularly measure. Samples are distributed by the Environmental Measurements Laboratory (EML) twice a year, and participants analyze both sets of samples. DOE monitoring organizations *should* participate in other interlaboratory QC programs such as the EPA Environmental Radioactivity Laboratory Intercomparison Studies Program (EPA-600/4-78-032).

Radiation measuring equipment, including portable instruments, environmental dosimeters, in situ monitoring equipment, and laboratory instruments, *should** be calibrated with standards traceable to NIST calibration standards (NCRP 1978; National Bureau of Standards Special Publication 609).